PATENT

Attorney Docket No.: 032286WN006

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Patent Application of:	)	
	)	
Roberto Alcantara Martins ZUCCHETTI, et. al.	)	
	)	
Appln. No.: 09/786,057	)	Group Art Unit: 1614
	)	
Filed: June 26, 2001	)	Examiner: R. J. Henley III

For : PROCESS AND COMPOSITION FOR ENHANCING THE ACTION OF VITAMIN A ON THE CELLULAR ACTIVITY OF AN INDIVIDUAL, AND USE OF VITAMIN C

APPEAL BRIEF

(1) Real Party in Interest

The present application is assigned to NATURA COSMETICOS S.A., a corporation of Brazil having a place of business at RUA AMADOR BUENO, 491, SANTO AMARO, 04752-900, SAO PAULO-SP, BRAZIL.

(2) Related Appeals and Interferences

To the best of the undersigned's knowledge, no other appeals or interferences will directly affect, will be directly affected by, or will have a bearing on the Board's Decision in this appeal.

(3) Status of Claims

Claims 1-7 and 11-20 remain pending in the application and are under appeal. These claims are attached to this Brief, as required by 37 C.F.R. § 1.192(c)(9).

(4) Status of Amendments

1) Appellants filed an Amendment (under 37 C.F.R. § 1.111) on April 24, 2002. This Amendment has been entered and made of record and has been considered by the Examiner.

2) Appellants filed an After-Final Amendment (under 37 C.F.R. § 1.116) on December 2, 2002. This Amendment has been entered and made of record and has been considered by the Examiner.

3) Appellants filed a Request for Continuing Examination and accompanying Amendment (under 37 C.F.R. § 1.111) on June 27, 2003. This Amendment has been entered and made of record and has been considered by the Examiner.

4) Appellants filed an Amendment (under 37 C.F.R. § 1.111) on February 9, 2004. This Amendment has been entered and made of record and has been considered by the Examiner.

5) Appellants filed an After-Final Amendment (Under 37 C.F.R. § 1.116) on October 21, 2004. This Amendment has been entered for the purposes of this Appeal and made of record and has been considered by the Examiner.

(5) Summary of Invention

The invention, according to claim 1, relates to a composition for enhancing the action of Vitamin A on the cellular activity of an individual. The composition includes a plurality of dispersed microspheres. Moreover, the plurality of microspheres include Vitamin A and an antioxidant inserted into a first group of microspheres, and Vitamin C inserted into a second group of microspheres. See Page 5, Lines 7-10. Furthermore, the microspheres are made of biologically active material. See Page 5, Lines 3-6.

Claim 2 limits the composition according to claim 1 to where the Vitamin C is present at a concentration of about 0.02% by weight, and the Vitamin A is present at a concentration of about 0.009% to 0.02% by weight, based on the total weight of the composition. See Page 4, Lines 20-24.

Claim 3 limits the composition according to claim 2 to where the Vitamin C is contained in the second group of microspheres at a concentration of 0.02%. See Page 5, Lines 9-14.

Claim 4 limits the composition according to claim 3 to where the first group of microspheres contains Vitamin A at an average concentration of about 0.014% by weight, based on the total weight of the composition. See Page 5, Lines 10-14.

Claim 5 limits the composition according to claim 4 to where the first group of microspheres contains Vitamin A at an average concentration of 0.014% and Vitamin E at an average concentration of 0.0005% by weight. See Page 5, Lines 9-14. Moreover, cosmetic compounds selected from the group consisting of skin structures, micronutrients of the skin, sensory agents, solar protection factors, emulsifiers, thickeners, sequestrants, antioxidants, fragrances, conservants, water and mixtures thereof. Furthermore, skin structures are squalan and sphingolipide complexes, the micronutrients of the skin is seaweed extract, and the sensory agents are selected from the group consisting of moisteners, emollients, and silicones. See Page 5, Lines 14-24.

Claim 6 limits the composition according to claim 1 to where the Vitamin C to Vitamin A weight ratio ranges from about 1:1 to about 10:1. See Page 4, Line 16.

Claim 7 limits the composition according to claim 1 to where the antioxidant is Vitamin E. See Page 5, Lines 7-8.

Claim 11 limits the composition according to claim 5 to where the moisteners are selected from the group consisting of glycerin, hydroxy prolisilan, and combinations thereof. See Page 5, Lines 14-21 (see specification as amended April 24, 2002 to insert the generic terminology of the Trademarks).

Claim 12 limits the composition according to claim 5 to where the emollients are selected from the group consisting of buthylene glycol, cethyl lactate, and combinations thereof. See Page 5, Lines 14-21.

Claim 13 limits composition according to claim 5 to where the silicone is cyclomethicone. See Page 5, Lines 14-21.

Claim 14 limits the composition according to claim 5 to where the solar protection factors are selected from the group consisting of butyl methoxydibenzoyl methane, 3-(4-methylbenzylidene) camphor, and combinations thereof. See Page 5, Lines 14-21.

Claim 15 limits the composition according to claim 5 to where the emulsifiers are selected from the group consisting of acrylates/C10-30 alkyl acrylate crosspolymer associated with trietanolamin, soybean lecitin, and combinations thereof. See Page 5, Lines 14-21.

Claim 16 limits the composition according to claim 5 to where the thickener is xanthan gum. See Page 5, Lines 14-21.

Claim 17 limits the composition according to claim 5 to where the sequestrant is ethylene diamine tetraacetate (EDTA). See Page 5, Lines 14-21.

Claim 18 limits the composition according to claim 5 to where the antioxidants are selected from the group consisting of buthyl hydroxytoluene (BHT), dl-α-tocopherol, and combinations thereof. See Page 5, Lines 14-21.

Claim 19 also concerns a composition for enhancing the action of Vitamin A on the cellular activity of an individual. The composition according to claim 19 includes a plurality of dispersed microspheres. The plurality of microspheres include Vitamin A and an antioxidant inserted into a first group of microspheres, and Vitamin C inserted into a second group of microspheres. See Page 5, Lines 7-10. Moreover, the microspheres are made of biologically active material. See Page 5, Lines 3-6. Furthermore, the Vitamin C is present in an amount effective for enhancing the action of the Vitamin A on the cellular activity of an individual. See Page 3, Lines 6-7 and Page 4, Lines 1-5.

Claim 20 also concerns a composition for enhancing the action of Vitamin A on the cellular activity of an individual. The composition of claim 20 includes a plurality of dispersed microspheres. The plurality of microspheres include Vitamin A and an antioxidant inserted into

a first group of microspheres, and Vitamin C inserted into a second group of microspheres. See Page 5, Lines 7-10. Moreover, the microspheres are made of biologically active material. See Page 5, Lines 3-6. Furthermore, the Vitamin C is present at a concentration of about 0.02% by weight and the Vitamin A is present at a concentration of about 0.009% to 0.02% by weight, based on the total weight of the composition. See Page 4, Lines 20-24.

(6) Issues

The following issue is presented for consideration in this appeal:

Did the Examiner commit reversible error in rejecting the claims under 35 U.S.C. § 103(a), as obvious based on Rinaldi et al. (U.S. Pat. No. 5,891,470) in view of Huc et al. (U.S. Pat. No. 5,395,620).

(7) Argument

The rejection under 35 U.S.C. §103(a) fails to establish *prima facie* obviousness.

The issue in this application concerns the Examiner's final rejection of the claims under 35 USC § 103(a), as purportedly obvious based on Rinaldi et al. (U.S. Pat. No. 5,891,470) in view of Huc et al. (U.S. Pat. No. 5,395,620).

Independent Claim 1 (from which claims 2-7 and 11-18 all ultimately depend) describes the Appellants' composition as a composition for enhancing the action of Vitamin A on the cellular activity of an individual. The composition includes a plurality of dispersed microspheres. Moreover, the plurality of microspheres include Vitamin A and an antioxidant inserted into a first group of microspheres, and Vitamin C inserted into a second group of microspheres. Furthermore, the microspheres are made of biologically active material.

Rinaldi discloses soft gel compositions wherein vitamin A and C are impregnated into microparticles. See Column 2, Lines 12-30; See Column 4, Line 58 – Column 5, Line 30. The soft gel compositions also include a silicone oil or silicone oil emulsion that is in contact with the

microparticles. As previously conceded by the Examiner, Rinaldi fails to teach or fairly suggest using biologically active microcapsules. In other words, the Examiner has conceded that Rinaldi's microparticles are not the same as the claimed microspheres made of biologically active material. Huc fails to remedy at least this deficiency of Rinaldi. Huc describes microcapsules which are not compatible with the composition described by Rinaldi. For example, if the microcapsules of Huc were placed in an oily medium (i.e. the silicone oil medium or oil emulsion medium used by Rinaldi), the vitamin A would permeate to the medium. Furthermore, if the microcapsules were placed in an aqueous medium, the vitamin C would permeate to the medium and, as a result, no longer protect the active ingredient in the formulation. In other words, the vitamin C would degrade. Accordingly, for the reasons described above, neither Rinaldi nor Huc provide the requisite motivation to those of ordinary skill in the art to modify the invention of Rinaldi with the teachings of Huc as suggested by the Office Action. This is because, as stated above, Huc's microcapsules are simply not compatible with the soft gel composition described by Rinaldi.

a) The teachings of Rinaldi and Huc teach away from one another.

Rinaldi and Huc actually teach away from the other. Rinaldi teaches that its soft gels are not compatible with water because the water will degrade the gelatin shell of the soft gel. See Column 1, Lines 40-45. Moreover, Rinaldi further teaches, "Suitable microparticles for this invention are solid, water-insoluble, polymeric microparticles." See Column 2, Lines 35-38. This is why Rinaldi specifically uses non-biologically active microparticles. In contrast, Huc teaches using particles which are biocompatible because they are made of atecollagen (a water soluble derivative of collagen). *See the Abstract.* Thus, Rinaldi specifically teaches away from using Huc's collagen containing particles as they would degrade. In other words, Huc's microcapsules are simply not compatible with soft gel formulations of Rinaldi.

Using Huc's collagen containing particles would actually ruin the composition of Rinaldi. The M.P.E.P. teaches, "If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984)." MPEP § 2143.01. Accordingly, not only does Rinaldi and Huc fail to provide the requisite motivation to those of ordinary skill in the art to modify the invention of Rinaldi with the teachings of Huc, there is also no reasonable expectation of success.

The Examiner has previously asserted that it is well known that vitamin C and vitamin E would permeate to their respective hydrophilic and hydrophobic environment and that the skilled artisan would take preventive measures. However, there is no teaching in either cited documents which suggests addressing the problem. Moreover, the Examiner fails to provide any evidence that those of ordinary skill in the art would recognize such problems and know how to compensate for them. It is the Appellants that have discovered a way to achieve a system which is capable of providing stability to the vitamin C in a aqueous medium and thus avoid the diffusion of vitamin A and vitamin C to the bulk formulation. Hence, this rejection is improperly based on hindsight. Moreover, it is improper to determine whether a person of ordinary skill would have been led to this combination of references based upon hindsight. In re Sang Su Lee, 277 F.3d 1338, 61 USPQ2d 1430 (Fed. Cir. 2002).

b) The specification shows a synergistic effect.

The present invention demonstrates the synergy between the ascorbic acid and retinol in the cellular activity. This effect is shown in the Figures and described in the instant specification. This effect was surprisingly detected by the present inventors since there was no indication of such technical result in the literature.

Rinaldi uses vitamin concentrations which are much higher than the present invention. The advantage provided by Appellants' invention with respect to using lower vitamin

concentrations is explained by the releasing mechanism of the microcapsules claimed in that patent. According to the teachings of Rinaldi, the vitamins are released on the skin surface and should permeate the skin until reaching the target sites. Upon permeating the skin, the vitamins (which are natural antioxidants) may be inactivated. Therefore, the actual vitamin concentration acting on the target sites is much lower than the concentration initially present in the formulation. Thus, an initial higher concentration must be used in the product disclosed by Rinaldi.

In contrast, the present inventors developed a formulation where a particular vitamin association has the effect on the cellular activity as shown in the graphs included in the present application. As they are substances that may undergo the above mentioned degradation in cosmetic formulations, microcapsules are employed to protect the vitamins.
In addition, when retinol is present on the skin surface it may cause serious damage to the user if that skin portion is exposed to the sunlight. This is a further drawback of the Rinaldi composition. Moreover, this is also another distinguishing advantage of Appellants' composition. In the present invention, the microcapsules are used in order to ensure that the vitamins will permeate the skin and reach their the target sites, wherein those microcapules are broken through enzymatic reactions, thus releasing the vitamins directly in the skin inner part.

The combination of Rinaldi and Huc would not have rendered the claimed invention obvious to those of ordinary skill. A proper *prima facie* case of obviousness does not entail the mere citing of references in an effort to show that one or more claimed elements, when viewed in a vacuum, are known. Rather, to establish a *prima facie* case of obviousness the Examiner must show how one skilled in the art would have found it obvious to choose elements or concepts from the various references so as to arrive at the claimed invention without using Appellant's own disclosure and claims as a guide. Ex parte Clapp, 227 USPQ 972 (BPAI 1985).

In Appellants' invention, microcapsules, which are made of biologically active material, are used in order to protect retinol and ascorbic acid and make it possible to prepare stable cosmetic compositions. Appellants' microparticles make preparation and packing much easier,

without the need of complex and expensive processes. In addition, because of the use of the microparticles, the water content of Applicants' formulation can be over 40%, which would normally be an appropriate medium for the degradation of ascorbic acid. However, degradation does not happen due to the presence of the microcapsules which act as a barrier for the contact of LAA with water.

As discussed above, Appellants' invention includes a first group of microparticles containing retinol and a second group of microparticles containing ascorbic acid. This second group, having a composition different from the first group, when contacted with the skin, penetrate the skin, and only release the contents thereof due to enzymatic reactions. Thus, retinol and ascorbic acid are released in a region very close to the target cells. Consequently, the retinol and ascorbic acid are not exposed to conditions that can lead to degradation (such as light, oxygen and water when on the skin, and water and free radicals when in the inner layers of the skin).

In view of the above, Appellants submit that those of ordinary skill in the art could come up with the present invention only after reading the present application. Thus, Appellants submit the rejection is improperly based on hindsight. This is because, as explained above, the teachings of these two cited patents would not have been sufficient to lead one of ordinary skill in the art to the present invention.

The requirement that to establish a *prima facie* case of obviousness, the Examiner must provide factual support from the cited patents for the proposed modification as been stressed by the courts. This factual support must be based on objective evidence of record and must establish that the cited patents themselves provide the requisite motivation, suggestion, or teaching regarding the desirability of making the specific combination made by the Appellant. The factual question of motivation is material to patentability, and can not be resolved on subjective belief and unknown authority. It is improper to determine whether a person of

ordinary skill would have been led to this combination of references based upon hindsight. In re Sang Su Lee, 277 F.3d 1338, 61 USPQ2d 1430 (Fed. Cir. 2002).

Dependents claims 2-7 and 11-18 contain al of the features of independent claim 1 and thus for at least the same reasons stated above are not rendered obvious by the combined teachings of Rinaldi and Huc.

Appellants make the following additional comments with respect to independent claims 19 and 20. Claim 19 states that the Vitamin C is present in an amount effective for enhancing the action of the Vitamin A on the cellular activity of an individual. Claim 20 states that the Vitamin C is present at a concentration of about 0.02% by weight, and the Vitamin A is present at a concentration of about 0.009% to 0.02% by weight, based on the total weight of the composition. Neither of these two features are taught or fairly suggested by Rinaldi or Huc. Moreover, contrary to the Examiner's assertion, the specification and Figures provide ample evidence showing the synergistic effect that occurs as a result of the claimed invention.

Appellants respectfully urge that the asserted rejection over Rinaldi and Huc is overcome, and withdrawal of the rejection is requested.

For the reasons set forth above, Appellants respectfully submit that the rejections under 35 U.S.C. § 103(a) of record is improper, and that the rejection of the claims is therefore overcome. Appellants therefore respectfully request that the rejection of the Examiner be reversed.

Respectfully submitted,

SMITH, GAMBRELL & RUSSELL, LLP

By: Brett A. Nelson Reg. No. 48,119
for Robert G. Weilacher, Reg. No. 20,531
1850 M Street, N.W., Suite 800
Washington, D.C. 20036
Telephone: (202) 263-4300
Fax: (202) 263-4329

Dated: February 22, 2005

(8) Appendix

Pursuant to 37 C.F.R. § 1.192(c)(9), this contains a clean copy of claims 1-6 and 8-10 which are the claims involved in this appeal.

Claim 1 (previously presented): A composition for enhancing the action of Vitamin A on the cellular activity of an individual, comprising a plurality of dispersed microspheres, said plurality of microspheres comprising Vitamin A and an antioxidant inserted into a first group of microspheres, and Vitamin C inserted into a second group of microspheres;
wherein said microspheres are made of biologically active material.

Claim 2 (previously presented): The composition according to claim 1, wherein Vitamin C is present at a concentration of about 0.02% by weight, and Vitamin A is present at a concentration of about 0.009% to 0.02% by weight, based on the total weight of the composition.

Claim 3 (previously presented): The composition according to claim 2, wherein Vitamin C is contained in the second group of microspheres at a concentration of 0.02%.

Claim 4 (previously presented): The composition according to claim 3, wherein the first group of microspheres contains Vitamin A at an average concentration of about 0.014% by weight, based on the total weight of the composition.

Claim 5 (previously presented): The composition according to claim 4, wherein the first group of microspheres contains Vitamin A at an average concentration of 0.014% and Vitamin E at an average concentration of 0.0005% by weight, and cosmetic compounds selected from the group consisting of skin structures, micronutrients of the skin, sensory agents, solar protection factors,

emulsifiers, thickeners, sequestrants, antioxidants, fragrances, conservants, water and mixtures thereof,

wherein said skin structures are squalan and sphingolipide complexes,

said micronutrients of the skin is seaweed extract, and

said sensory agents are selected from the group consisting o f moisteners, emollients, and silicones.

Claim 6 (previously presented): The composition according to claim 1, wherein the Vitamin C to Vitamin A weight ratio ranges from about 1:1 to about 10:1.

Claim 7 (previously presented): The composition according to claim 1, wherein the antioxidant is Vitamin E.

Claim 11 (previously presented): The composition according to claim 5, wherein the moisteners are selected from the group consisting of glycerin, hydroxy prolisilan, and combinations thereof.

Claim 12 (previously presented): The composition according to claim 5, wherein the emollients are selected from the group consisting of buthylene glycol, cethyl lactate, and combinations thereof.

Claim 13 (previously presented): The composition according to claim 5, wherein the silicone is cyclomethicone.

Claim 14 (previously presented): The composition according to claim 5, wherein the solar protection factors are selected from the group consisting of butyl methoxydibenzoyl methane, 3-(4-methylbenzylidene) camphor, and combinations thereof.

Claim 15 (previously presented): The composition according to claim 5, wherein the emulsifiers are selected from the group consisting of acrylates/C10-30 alkyl acrylate crosspolymer associated with trietanolamin, soybean lecitin, and combinations thereof.

Claim 16 (previously presented): The composition according to claim 5, wherein the thickener is xanthan gum.

Claim 17 (previously presented): The composition according to claim 5, wherein the sequestrant is ethylene diamine tetraacetate (EDTA).

Claim 18 (previously presented): The composition according to claim 5, wherein the antioxidants are selected from the group consisting of buthyl hydroxytoluene (BHT), dl-α-tocopherol, and combinations thereof.

Claim 19 (previously presented): A composition for enhancing the action of Vitamin A on the cellular activity of an individual, comprising a plurality of dispersed microspheres, said plurality of microspheres comprising Vitamin A and an antioxidant inserted into a first group of microspheres, and Vitamin C inserted into a second group of microspheres;
wherein said microspheres are made of biologically active material, wherein the Vitamin C is present in an amount effective for enhancing the action of the Vitamin A on the cellular activity of an individual.

Claim 20 (previously presented): A composition for enhancing the action of Vitamin A on the cellular activity of an individual, comprising a plurality of dispersed microspheres, said plurality

of microspheres comprising Vitamin A and an antioxidant inserted into a first group of microspheres, and Vitamin C inserted into a second group of microspheres;

wherein said microspheres are made of biologically active material, and Vitamin C is present at a concentration of about 0.02% by weight, and Vitamin A is present at a concentration of about 0.009% to 0.02% by weight, based on the total weight of the composition.

AF

PTO/SB/17 (12-04v2)
Approved for use through 07/31/2006. OMB 0651-0032
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Effective on 12/08/2004.
Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).

FEE TRANSMITTAL for FY 2005

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT ($) **500.00**

Complete If Known	
Application Number	**09/786,057**
Filing Date	**June 26, 2001**
First Named Inventor	**Roberto A.M. ZUCCHETTI, et al.**
Examiner Name	**Raymond J. Henley III**
Art Unit	**1614**
Attorney Docket No.	**032286W006**

METHOD OF PAYMENT (check all that apply)

☒ Check ☐ Credit Card ☐ Money Order ☐ None ☐ Other (please identify) : _____

☒ Deposit Account Deposit Account Number: **02-4300** Deposit Account Name: **Smith, Gambrell & Russell**

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

☐ Charge fee(s) indicated below ☐ Charge fee(s) indicated below, **except for the filing fee**

☒ **Charge any additional fee(s) or underpayments of fee(s) Under 37 CFR 1.16 and 1.17** ☒ **Credit any overpayments**

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FEE CALCULATION

1. BASIC FILING, SEARCH, AND EXAMINATION FEES

	FILING FEES		SEARCH FEES		EXAMINATION FEES		
		Small Entity		Small Entity		Small Entity	
Application Type	Fee ($)	Fee($)	Fee($)	Fee($)	Fee($)	Fee($)	Fees Paid ($)
Utility	300	150	500	250	200	100	____
Design	200	100	100	50	130	65	____
Plant	200	100	300	150	160	80	____
Reissue	300	150	500	250	600	300	____
Provisional	200	100	0	0	0	0	____

2. EXCESS CLAIM FEES

Fee Description	Fee ($)	Small Entity Fee ($)
Each claim over 20 (including Reissues)	50	25
Each independent claim over 3 (including Reissues)	200	100
Multiple dependent claims	360	180

Total Claims		Extra Claims	Fee($)		Fee Paid ($)
____	-20 or HP=	____	x ____	=	____

HP = highest number of total claims paid for, if greater than 20.

Indep. Claims		Extra Claims	Fee($)		Fee Paid ($)
____	- 3 or HP=	____	x ____	=	____

HP = highest number of independent claims paid for, if greater than 3.

Multiple Dependent Claims	
Fee ($)	Fee Paid ($)
____	____

3. APPLICATION SIZE FEE

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets		Extra Sheets		Number of each additional 50 or fraction thereof	Fee ($)	Fee Paid ($)
____	- 100 =	____	/ 50 =	____ (round up to a whole number) x		= ____

4. OTHER FEE(S)

	Fees Paid ($)
Non-English Specification, $130 fee (no small entity discount)	____
Other (e.g., late filing surcharge) : **Appeal Brief**	**$500**

SUBMITTED BY

Signature	Brutus Reb Reg. No. 48,109	Registration No. (Attorney/Agent)	20,531	Telephone	202/263-4300
Name (Print/Type)	Robert G. Wellacher			Date	February 22, 2005